

REMARKS

Claims 3, 11, 14, and 15 were rejected under 35 U.S.C. 112, second paragraph. Claim 3 has been cancelled. The rejections are respectfully traversed with respect to the remaining claims.

In particular, claims 3, 11, 14, and 15 were rejected because the Examiner asserts that certain terms were "inferentially claimed" and thus vague. Applicants respectfully assert the claims in question are sufficiently clear for one of ordinary skill in the art to interpret them and as such, a rejection under 35 U.S.C 112, second paragraph is improper. MPEP 2173. Furthermore, whether or not the terms in question are inferentially claimed is irrelevant as that is not a proper basis for rejecting a claim in the first place. Should the Examiner maintain such a rejection, Applicants respectfully request specific legal support for making a rejection based upon "inferential claiming". The elements in question are part of the claim, they are clear, and should be examined.

The Examiner appears to be focusing on form rather than substance when evaluating the terms in question. The mere inclusion of a term within the body of a claim without first setting that term off as a separate element or paragraph most certainly does not render the claim vague. For example, claim 11 includes "wherein the elongated body is further coupled to a sensor to sense a physiological signal." The "body" is "coupled" to "a sensor". No reasonable person having ordinary skill in the art could possibly have any doubt as to what this language means and what is being claimed. As such, the rejection and those like it are wholly improper and must be withdrawn.

Applicant will not make unnecessary claim amendments simply because the Examiner would prefer to see language presented in another format. "The Examiner's focus during Examination of claims for compliance with the requirement for definiteness of 35 U.S.C 112, second paragraph is whether the claim meets the threshold requirements of clarity and precision, ***not whether more suitable language or modes of expression are available.***" MPEP 2173.02. (Emphasis added).

Certain claims were rejected under 35 U.S.C 102(b) as being anticipated by either Termin or Jaraczewski. Those rejections have been rendered moot by the present claim amendments. Specifically, claim 1 has been amended to include variations of previous claims 2 and 3, now both cancelled. Independent claims 20 and 31 have been similarly amended.

The remaining relevant rejection of these claims is the combination of Jaraczewski and Bens et al. under 35 U.S.C 103(a). Jaraczewski teaches a single piece, elongated electrode array 2 that is insertable into a catheter body 4. The electrode array includes a shaped distal end such that upon passing through the distal end of the catheter, the electrode array can be placed against a larger surface area of tissue for mapping or ablation. The electrode array is a temporary device that will not be affixed to the tissue or within a vessel. That is, the tip is never screwed into tissue or anchored in a vessel; rather it is placed against cardiac tissue for mapping or ablation. As such, it is important to provide maximum control and the ability to controllably and selectively apply force or pressure to the distal end.

Bens et al. teach a lead having a spiral tip that is smaller than the diameter of the lead body. Rotation of a member within the lead body allows the spiral tip to be advanced for fixation.

Despite the Examiner's unsupported assertions, the devices taught by Bens et al. and Jaraczewski are not properly combinable. Bens et al. teach a lead that is permanently affixed. Jaraczewski teaches a catheter and electrode assembly used for a temporary procedure such as mapping or ablation. The Jaraczewski device would not include a fixation tip and the Bens device would not be used for mapping/ablation. The Examiner's alleged motivation to use a stylet to "more easily" advance the helical electrode of Jaraczewski is without merit and cannot be substantiated. As mentioned, the unitary electrode member of Jaraczewski provides maximum control, ease of use, and allows the selective application of pressure as the electrode array is positioned and repositioned within the heart. Thus, the use of the Bens et al. structure would lead to a less useful, less efficient, device that is harder to operate and is unoperative for the purposed

disclosed by Jaraczewski. Thus, one of ordinary skill in the art would not be motivated make such a combination.

Furthermore, the Jaraczewski reference teaches the use of a separate catheter element through which various tools, such as the electrode array are inserted. By using the Bens arrangement, the electrode array would then be the only tool used and a completely different device would have to be inserted for other operations. For example, one such electrode array may be used for mapping, another for ablation, while still other assemblies may be inserted through the catheter for other operations. This provides yet another reason why such a combination is improper.

The Bens et al. device does not allow for the insertion of different elements (e.g. different electrode arrays) nor does it allow for the full retraction of any such device as is required in the Jaraczewski device. The rotation of the tip in the Bens device allows the tip to be advanced and retracted into and out of the distal tip of the catheter; no more. Thus, the Bens teachings are incompatible with Jaraczewski.

The Jaraczewski reference does not teach the use of a helical tip for affixation, either through boring into tissue or expanding within a vessel wall, as is presently claimed. Thus, even if the combination were made, the resultant combination does not teach the presently claimed invention. As such, the claims are not rendered obvious by the present combination nor by any combination of references of record. The remaining claims depend from those addressed herein and are allowable for at least the same reasons.

Applicant respectfully asserts that the present claims are in condition for allowance and notice of the same is respectfully requested. Should any issues

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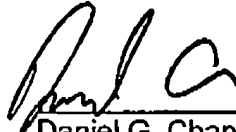
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remain, the Examiner is requested to telephone the undersigned attorney to expedite prosecution.

Respectfully submitted,

Date: 10/17/03



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